

Section 5 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS***510(k) Summary of safety and effectiveness***

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Acacia, Inc.
APPLICANT ADDRESS	785 Challenger Street Brea, CA 92821
APPLICANT PHONE	(714) 257-0470
CONTACT PERSON	Fergie Ferguson
PREPARATION DATE	01/11/12
TRADE NAME:	Medi-SIS Syringe Infusion System
COMMON NAME:	Infusion Pump
CLASSIFICATION NAME:	Infusion Pump
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	FRN, LZH
PREDICATE DEVICES:	Medi-SIS Syringe Infusion System (K953028, K954059, K972173) B. Braun Perfusor Space Infusion Syringe Pump System (K062699)

Purpose

The purpose of this submission is to add the delivery of enteral fluids through clinically accepted routes of administration to the intended use. No changes to the design of the device or performance features were made.

Substantially Equivalent To:

The Acacia, Inc. Medi-SIS Syringe Infusion System is substantially equivalent in intended use, principle of operation and technological characteristics to the Medi-SIS Syringe Infusion System (K953028, K954059, K972173), and is substantially equivalent in intended use with the B. Braun Perfusor Space Infusion Syringe Pump System (K062699) for the delivery of enteral fluids.

Description of the Device Subject to Premarket Notification:

The Medi-SIS Syringe Infusion System consists of a Syringe Driver (mechanical syringe pump), proprietary administration extension set, and compatible syringe.

The Medi-SIS Syringe Driver consists of a mechanical syringe pump assembly that is manufactured from plastic housings and end caps, and steel spring (mechanical force from the spring presses against the syringe plunger), and holds a 30mL or 60mL Becton Dickinson syringe (preamendment device) or a 30mL or 60mL Acacia syringe (K092986). The Medi-SIS Syringe Driver must be used in conjunction with a Medi-SIS Administration Extension Set, which controls the time the infusion will occur (by flow restrictor) for the entire volume of the filled syringe. The

Section 5 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Medi-SIS Syringe Infusion System infuses fluids in a continuously decreasing rate and the user can calculate the average flow rate based from volume and time infused.

The Medi-SIS Syringe Driver is reusable and provided non-sterile.

The Medi-SIS Administration Set consists of various lengths of flexible non-DEHP PVC tubing, on/off clamp, flow restrictor, and male and female connectors. The male and female connectors meet Acacia's internal specifications for enteral applications to ensure cross connections do not occur between IV and Enteral infusions. Additional componentry may be added and configurations modified based on the needs of clinicians.

The following Administration Extension Sets will be available:

60mL Syringe Size, 1.0mL per minute delivery rate
60mL Syringe Size, 2.0mL per minute delivery rate
30mL Syringe Size, 0.5mL per minute delivery rate
30mL Syringe Size, 1.0mL per minute delivery rate
30mL Syringe Size, 2.0mL per minute delivery rate

The approximate residual volume for the syringe/administration extension set combination is approximately 2.20mL for all configurations. The Medi-SIS Administration Extension Set is provided sterile, single use, and non-pyrogenic.

Indications for Use:

1. The Medi-SIS Syringe Infusion System is indicated for the delivery of enteral fluids through clinically accepted routes of administration.
2. The Medi-SIS Administration Extension Set is intended for single patient use only.
3. The Medi-SIS Syringe Driver can be reused up to 5,000 times

Technical Characteristics:

Other than differences in connector sizes between the Medi-SIS Administration Extension Sets for IV and Enteral applications (to ensure cross connections do not occur between IV and Enteral infusions), the Medi-SIS Syringe Infusion System is identical to the predicate device (the same Syringe Driver, tubing, and flow restrictor will be used), along with the same compatible syringes. There are no differences in design, material, chemical composition, or any other physical (other than connector sizes) and technical characteristics to the predicate device.

Performance Data:

A human factors study was conducted to assess the clinical risks related to the use of the Medi-SIS Syringe Infusion System for enteral feeding of neonatal patients by the hospital NICU staff. All identified risks have been identified and adequately mitigated to ensure the system is safe for use.

The following non-clinical tests were performed to ensure the device is capable of meeting the predicate device's specifications when tested for the addition of enteral fluids to the intended use:

Section 5 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

- Enteral fluid delivery within the specified time
- Maximum residual volume

Since the addition of enteral fluid delivery was the only difference between the proposed and the predicate device, the significant test to ensure equivalency was to test the delivery time of enteral fluids and to verify they met the predicate device's specifications. The testing concluded that the device met all of the specifications.

Since the proposed and predicate devices are the same, it is concluded that the proposed device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device.

Basis for Determination of Substantial Equivalence:

Since the only change to the predicate device was to add the delivery of enteral fluids through clinically accepted routes of administration to the intended use, and to differentiate the connectors between the IV and Enteral Medi-SIS Administration Extension Sets, it was concluded that the differences do not affect the performance specifications of the predicate device and do not add new hazards that would pose a safety risk to the patient or clinician. Verification was performed to ensure that the testing with an equivalent enteral fluid standard met all of the predicate device specifications.

Upon reviewing the safety and efficacy information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the Medi-SIS Syringe Infusion System is determined by Acacia, Inc., to be substantially equivalent to the existing legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
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Ms. Fergie Ferguson
Director of Operations
Acacia, Incorporated
785 Challenger Street
Brea, California 92821

JAN 13 2012

Re: K111381

Trade/Device Name: Medi-SIS Syringe Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: January 6, 2012
Received: January 9, 2012

Dear Ms. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

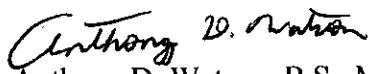
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111381

Device Name: Medi-SIS Syringe Infusion System

Indications for Use:

- 1.0 The Medi-SIS Syringe Infusion System is indicated for the delivery of enteral fluids through clinically accepted routes of administration.
- 2.0 The Medi-SIS Administration Extension Set is intended for single patient use only.
- 3.0 The Medi-SIS Syringe Driver can be reused up to 5,000 times

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RJ C Chp 1/13/12
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111381